Bryn Pharma to Present Positive Clinical Data Supporting Use of Its Epinephrine Nasal Spray in Adults with or without Congestion at 2023 ACAAI Annual Meeting

~ Results showed that NDS1C provides enhanced absorption in adults with or without congestion compared to current first-line intramuscular epinephrine and autoinjector administered treatments ~

~ The study also found that NDS1C was safe and generally well-tolerated; if approved, NDS1C may offer patients at risk of anaphylaxis a practical alternative to needle-based administration routes ~

Lebanon, NJ – November 9, 2023 – Bryn Pharma, LLC, a privately held pharmaceutical company dedicated to finding a novel and convenient way for patients and caregivers to treat anaphylaxis, announced today that positive clinical data supporting use of its epinephrine nasal spray (ENS) – known as NDS1C – in adults with or without congestion, will be presented during the 2023 American College of Allergy Asthma and Immunology Annual Scientific Meeting (ACAAI). The meeting is being held November 9-13, 2023, in Anaheim, California.

The open-label study aimed to demonstrate that in real-world settings, nasal congestion, which is a common symptom of various medical conditions, including anaphylaxis, does not negatively affect the absorption and bioavailability of NDS1C. The results showed that NDS1C, in fact, provides enhanced absorption in adults with or without congestion compared to intramuscular (IM) epinephrine and the epinephrine autoinjector (EAI). Currently, IM/EAI administration of epinephrine are first-line treatments of anaphylaxis.

“This study further validates the clinical utility of NDS1C, showing it not only offers improved absorption of active drug compared to currently available products on the market, but also offers patients at risk of anaphylaxis a potentially safe and effective alternative to needle-based administration,” said Sandy Loreaux, chief executive officer at Bryn Pharma. “Unlike other epinephrine nasal spray candidates in development, NDS1C is the only intranasal epinephrine product with publicly available data demonstrating enhanced absorption in the presence of congestion. We are pleased that our development program continues to demonstrate that congestion does not have a negative impact on the pharmacokinetic profile of NDS1C.”

Safety results from the study found that NDS1C was safe and generally well-tolerated. There were minimal treatment effects on heart rate and systolic/diastolic blood pressure, with no correlation between drug concentration and these effects observed. Treatment-emergent adverse event (AE) incidences with 13.2 mg NDS1C with and without nasal allergy challenge (NAC) in opposite nostrils were 54% and 64%, respectively, and in the same nostril were 44% and 48%, respectively. The most common AEs were mild nausea and headache.

“Patients and families are in need of an efficient epinephrine delivery device that simply does not involve needles,” said Michael Blaiss, MD, clinical professor of pediatrics at Medical College of Georgia and past president of ACAAI. “As a clinician, it is highly encouraging to see data demonstrating that intranasally administered epinephrine actually leads to enhanced absorption of this life-saving drug in people with congestion compared to the currently available intramuscular and autoinjector options. If approved, NDS1C will be a welcomed alternative to healthcare professionals to help this community address the inherent challenges that come with using injection therapy so they can better manage their daily lives.”

Study Design:
The open-label, four-period, four-treatment, partial-crossover study evaluated 50 healthy adults with confirmed seasonal allergies. Participants were enrolled in either the opposite nostrils ENS cohort or the same nostril ENS cohort. In the first period, both cohorts received 13.2 mg of NDS1C administered by two consecutive sprays, with congestion induced by NAC. During the second and third periods, both cohorts were administered 0.3 mg epinephrine by IM autoinjector or 0.5 mg epinephrine IM by manual syringe (MS). The fourth period included 13.2 mg ENS (NDS1C) administered by two consecutive sprays, without congestion. The study included a washout period of one day between Periods 1-3 and of at least 14 days between Periods 1 and 4. All treatments were administered by trained clinical personnel.

The poster can be accessed here and presentations details are as follows:

- **Poster**: #P8080
- **Title:** 13.2 mg Intranasal Epinephrine Treatment In Congestion Shows Increased Bioavailability Without Pharmacokinetic And Pharmacodynamic Correlation
- **Date & Time:** Friday, November 10 at 3:15 p.m. PT

About NDS1C
If approved, NDS1C will offer patients a novel delivery system for emergency epinephrine, an area that hasn’t seen significant innovation in fifty years. In 1987, the FDA approved the first epinephrine autoinjector, which has since become the standard of care in outpatient settings. Today, Bryn is working to continue the path of innovation by advancing a development program focused on efficacy and safety comparisons of NDS1C to the current standard of care treatment, the 0.3 mg IM autoinjector, in accordance with clinical practice guidelines. Bryn is dedicated to creating a novel and practical solution to help this community address these challenges and better manage their daily lives with severe allergies.

About Bryn Pharma
Bryn Pharma, established in 2017, is a privately held pharmaceutical company founded by patients for patients. Bryn is focused on positively disrupting the existing market for epinephrine autoinjectors by delivering an accessible, easy-to-use alternative that better meets the needs of patients. Bryn Pharma seeks to provide this growing population at risk for anaphylaxis with a novel and practical way to be prepared for a life-threatening allergic reaction. For more information visit www.brynpharma.com.

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